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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
09/754,010	01/03/2001	Mark E. Dillon	E-1950	3438		
7590	06/11/2007	<table border="1"><tr><td>EXAMINER</td></tr><tr><td>LANDAU, SHARMILA GOLLAMUDI</td></tr></table>			EXAMINER	LANDAU, SHARMILA GOLLAMUDI
EXAMINER						
LANDAU, SHARMILA GOLLAMUDI						
John F. A. Earley III 86 The Commons At Valley Forge East 1288 Valley Forge Road P.O. Box 750 Valley Forge, PA 19482-0750		ART UNIT	PAPER NUMBER			
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		MAIL DATE	DELIVERY MODE			
		06/11/2007	PAPER			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	09/754,010	DILLON, MARK E.
	Examiner	Art Unit
	Sharmila Gollamudi-Landau	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 May 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 34-54 is/are pending in the application.
 4a) Of the above claim(s) 46-54 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 34-45 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Request for Continued Examination and Amendments/Remarks filed 5/1/07 is acknowledged.

Election/Restrictions

Newly submitted claims 50-54 drawn to a method of manufacturing a wound dressing, classified in class 602, 46 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product can be used as a transdermal product to deliver drugs. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46-49 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 34-45 are directed to the constructively elected invention. Claims 46-54 are withdrawn as being directed to the non-elected invention.

Claim Rejections - 35 USC § 112

The rejection of claim 41 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 34-36 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindqvist et al (6,051,747).

Lindqvist et al disclose a wound dressing a gel layer (3), which is reticulated into a polyurethane foam layer (2) with open cells (fenestrations) and a thickness of 1-10mm (1000microns to 10,000 microns), and a liquid impervious layer made of a polyurethane film (5). See Figures. The gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the wound, excess wound fluid can be drawn into the foam material 2 and absorbed thereby. The polyurethane film is glued to the foam layer. See column 5, lines 63-65. The polyurethane film has high vapor permeability and a thickness of 0.025 mm (25 microns). See column 5, lines 63-65. Note that the polyurethane film in this embodiment read on the instant membrane layer since “membrane” is defined as “a thin sheet of natural or synthetic material”. Note also in this embodiment the glue reads on the adhesive layer since the glue acts to bond the foam and the film.

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With regard to lines 4-9 of independent claim 34, it is the examiner's position that since Lindqvist discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the wound dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

Response to Arguments

Applicant argues that although Lindqvist discloses a gel layer and an absorbent foam, Lindqvist does not suggest or discloses a dual purpose wound dressing with disparate wound healing characteristic. Applicant argues that Lindqvist disclose that the foam layer is sandwiched between two layers, i.e. the gel layer and the liquid impervious layer. Thus, applicant argues that the instant invention is structurally distinguishable from the prior art. Applicant argues that the prior art does not teach using the wound dressing in the instant "upside down manner".

Applicant's arguments filed 5/1/07 have been fully considered but they are not persuasive. The examiner points out that the instant invention is directed to a product and not the method of use; thus the determination of patentability is based on the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer. The examiner points out that the prior art discloses a 1a foam layer that is not occluded by the gel and 2) a polyurethane foam layer in Figure 2. The examiner points out that the foam layer is not sandwiched as argued by applicant since Lindqvist's clearly discloses that the "gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the wound" See column 2, lines 50-53. Thus, the foam does have a wound-contacting

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surface since the gel layer or adhesive layer does not cover the entire surface of the foam layer. Therefore, Lindqvist's structure and the instant invention as claimed are not structurally distinguishable and the prior art's wound dressing is capable of performing the recited intended use. Meaning the wound dressing is capable of being used upside down. Again the examiner points out that the claimed intended use of the dressing, i.e. using in an upside down manner, does not impart a structural difference since the prior art may also be turned upside down since it has a foam layer and a membrane layer.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, 36, 40, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofeditz et al (4,552,138).

Hofeditz et al disclose a dressing material comprising at least one layer of hydrophilic, transparent polymeric gel (see column 2, lines 44-45) and a carrier material. Example 5 discloses the gel layer laminated to an open-pore (fenestrations) polyurethane foam. Hofeditz discloses the additional use of dyes and pigments. See claim 13 and examples.

It should be noted that membrane is defined as a "thin, soft pliable sheet or layer"; thus Hofeditz polymeric gel layer reads on "membrane layer".

With regard to lines 4-9 of independent claim 34, it is the examiner's position that since Hofeditz discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the wound dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

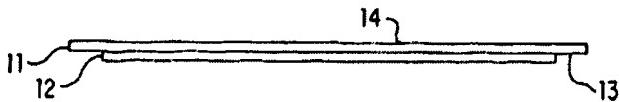
Response to Arguments

Applicant argues although Hofeditz has a gel layer having an outer wound-contacting surface, Hofeditz, in contrast to Applicant's invention, has a foam layer as an intermediate or cover layer. Hofeditz does not disclose a foam layer having an outer wound contacting surface having wound healing characteristics, as called for by Applicant's claim 34.

Applicant's arguments filed 5/1/07 have been fully considered but they are not persuasive. The examiner points out that the instant invention is directed to a product and not the method of use; thus the determination of patentability is based on the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer. The examiner points out that the prior art discloses a 1) a gel layer that reads on the membrane layer since a membrane is defined as a "thin, soft pliable sheet or layer" and 2) a polyurethane foam layer. Thus, since Hofeditz's structure and the instant invention as claimed are not structurally distinguishable, the prior art's wound dressing is capable of performing the recited intended use. Meaning the wound dressing is capable of being used upside down. Again the examiner points out that the claimed intended use of the dressing, i.e. using in an upside down manner, does not impart a structural difference since the prior art may also be turned upside down since it has a foam layer and a membrane layer.

Claims 34-36, 38, 42-43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (5,681,579).

Freeman discloses a polymeric support wound dressing. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) bonded by adhesives (13) means to a hydrocolloid containing polymeric layer (12) (first layer).



The occlusive layer 11 has an upper or outer surface 14, which is open to the atmosphere and an inner surface 13, which is the side toward the skin. The occlusive layer is preferably a polyurethane foam. See column 4, lines 30-31. The adhesive layer may for example extend across the entire under surface 13 of the occlusive layer or only a portion of it. The polymeric support layer 12 is any polymeric material useful in medical settings and is in the form of a web, net, perforated film or perforated layer. The polymeric support layer 12 contains a hydrocolloid either blended with the polymeric material. When the hydrocolloid is blended with the polymeric material it is preferred that the two materials be extruded together to form a film. See column 5, lines 1-30. It should be noted that a membrane is defined as a "thin, soft pliable sheet or layer"; thus Freeman's polymeric support reads on instantly claimed "membrane layer". The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8. The adhesive layer is made of various substances including silicone rubber. See column 6, line 31.

Dressing A discloses a hydrocolloid centered on polyurethane foam, which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45.

With regard to lines 4-9 of independent claim 34, it is the examiner's position that since the prior art discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the wound dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended

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use. Moreover, a portion of layer 11, the foam, along with layer 12, contacts the skin surface as disclosed by Freeman on column 4, lines 13-15.

Response to Arguments

Applicant argues that the instant invention is directed to novel wound dressing that has two wound contacting layers each with its own wound healing characteristics. Applicant argues that the occlusive layer does not contact the wound surface since it has an adhesive layer that covers its overhanging portion.

Applicant's arguments filed 5/1/07 have been fully considered but they are not persuasive. Applicant's arguments are unclear. The examiner points out that the instant invention is directed to a product and not the method of use; thus the determination of patentability is based on the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer, 2) an adhesive layer, and 3) a foam layer. The prior art discloses a 1) polymeric membrane layer, 2) an adhesive layer, and 3) a polyurethane foam layer. Thus, since Freeman's structure and the instant invention as claimed are not structurally distinguishable, the prior art's wound dressing is capable of performing the recited intended use. T

The examiner further points out that the instant disclosure states that using the instant invention "upside down" provides the dual purpose; thus Freeman's dressing is also capable of being turned "upside down" to provide the dual function.

Applicant discloses on page 5, lines 22-25:

"By applying the dressing to the wound site with the IPN surface against the wound surface...."

On page 6, lines 4-12, applicant discloses:

"I have discovered that the dressing...is also useful when used up-side down with the foam layer against the wound instead of the IPN layer."

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The examiner notes that depending on which side one desires to contact the wound, the prior art, which is structurally indistinguishable, can also be flipped accordingly.

Moreover, a portion of layer 11 (foam occlusive layer) contacts the skin. The examiner points out that Freeman discloses that the adhesive layer may be applied to only a portion of layer 11. Therefore, the overhanging portion of layer 11 as seen in Figure 1, does in fact, contact the wound as disclosed by Freeman on column 4, lines 13-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 37, 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) in view of Lorenz et al (5,258,421) and as evidenced by US 4832009.

The disclosure of Lindqvist has been set forth above.

Lindqvist does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer. Further, the addition of a pigment is not taught.

Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate. The backing substrate provides liquid barrier properties and may be a polymer film such as polyurethane film or silicone-polytetrafluoroethylene IPN membrane film. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist et al and Lorenz et al and replace Lindqvist's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have Liquid barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in Lindqvist's wound dressing over Lindqvist's polyurethane film for the advantages taught by

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Lorenz, i.e. if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site. A skilled artisan would have reasonably expected success and similar results since Lorenz teaches both Lindqvist's polyurethane film and instant silicone-polytetrafluoroethylene IPN function in a similar manner, i.e. functional equivalents (both are liquid impervious layers that are utilized in wound dressing).

With regard to claim 40, it would have been obvious to add a pigment to Lindqvist's gel if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

With regard to claim 41, it is noted that polymeric film layers are implicitly translucent unless a pigment is added. Further, it should be noted that US '009 substantiates the examiner's position that the silicone-polytetrafluoroethylene IPN are transparent. Note column 1, lines 55-60 of US '009. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered *prima facie* obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

With regard to claim 42, pores (fenestrations) are a property of silicone-polytetrafluoroethylene IPN films. US '009 substantiates this. Note column 1, lines 45-60 of US '009.

Response to Arguments

Applicant argues that Lindqvist does not teach using the wound dressing in the instant manner; i.e. an upside down manner. Applicant argues that this use is gleaned from applicant. Applicant argues that Lorenz does not teach a dual surface wound dressing and the IPN layer is merely provided to protect the gel and not contact the skin.

Applicant's arguments filed 5/1/07 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In instant case, applicant has not addressed the examiner's motivation to combine the references and has rather analyzed each reference separately. The examiner points out that the primary reference is not deficient in the teaching of a foam layer and thus Lorenz does not need to teach a foam layer. The premise of the rejection is Lorenz provides the motivation to substitute Lindqvist's polyurethane film with the instant IPN film by teaching both are functional equivalents. Applicant has not provided any arguments or evidence of the unobvious difference. Again, applicant is arguing the intended use of the wound dressing and the examiner points out that intended use is not given patentable weight unless it imparts a structural difference. In instant case, it does not. The prior art, Lindqvist teaches a two-layer wound dressing as claimed and thus is capable of performing the intended use.

Applicant argues that the addition of the pigment is not merely a design change but functions as a visual indicator differentiating one side from the other.

The examiner notes that the addition of the pigment is a structural change. The examiner has not attempted to argue that it does not. The examiner has merely pointed out that adding a pigment to a layer does not change the mechanism of the wound dressing, i.e. providing a non-obvious dressing. It is the examiner's position that adding a pigment in view of Lorenz's teachings is obvious since one would add a dye to impart a desired color.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) by itself or in view of Freeman (5,681,579).

The disclosure of Lindqvist has been set forth above. The reference teaches the foam has a thickness of 1-10mm (1000microns to 10,000 microns), and a liquid impervious layer (polyurethane film) has a thickness of 0.025 mm (25 microns).

Lindqvist does not teach the instant thickness of the membrane layer, i.e. 50 microns.

Freeman teaches a polymeric support wound dressing, which comprises a occlusive layer and a support layer. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) is preferably a polyurethane foam bonded by adhesives (adhesive layer) means to a perforated film (12) (first layer). See also column 4 to column 5 and examples. Dressing A discloses a hydrocolloid centered on a polyurethane foam, which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45. The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Lindqvist and manipulate the thickness of the liquid impervious layer from 25 microns to 50 microns. One would have been motivated to manipulate the thickness of this layer since the polymeric layer functions to support the foam

layer. Thus, depending on factors such as the weight and thickness of the foam layer one would have been motivated to utilize the appropriate thickness to support the foam layer and provide strength to the entire structure.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist and Freeman and manipulate the thickness of the liquid impervious layer from 25 microns to 50 microns. One would have been motivated to do so since Freeman teaches polyurethane films may be in a thickness of 35-76 microns. Therefore, a skilled artisan would have been motivated to manipulate the thickness of this layer since the polymeric layer functions to support the foam layer. Thus, depending on factors such as the weight and thickness of the foam layer one would have been motivated to utilize the appropriate thickness to support the foam layer and provide strength to the entire structure.

Claims 37, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz et al (5,258,421) and as evidenced by US 4832009.

The disclosure of Freeman has been set forth above.

Freeman does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer or a pigment.

Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound

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dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, the backing substrate may be covered by a silicone-coated release-liner. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Freeman et al and Lorenz et al and replace Freeman's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have Liquid barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in the wound dressing over Freeman's polyurethane film for the advantages taught by Lorenz, i.e. if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site.

With regard to claim 40, it would have been obvious to add a pigment to the gel if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

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With regard to claim 41, it is noted that polymeric film layers are implicitly translucent unless a pigment is added. Further, it should be noted that US '009 substantiates the examiner's position that the silicone-polytetrafluoroethylene IPN are transparent. Note column 1, lines 55-60 of US '009. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered *prima facie* obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

Response to Arguments

Applicant argues the combination of Freeman and Lorenz only teaches a single sided dressing and cannot be used in the instant manner.

Applicant's arguments filed 5/1/07 have been fully considered but they are not persuasive. The merits of Freeman have been discussed above under the anticipation rejection and thus the examiner's response to applicant's arguments is incorporated herein. Therefore, Freeman in view of Lorenz is considered to render the instant invention obvious.

Applicant argues that the addition of the pigment is not merely a design change but functions as a visual indicator differentiating one side from the other.

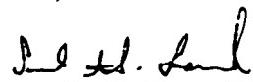
The examiner notes that the addition of the pigment is a structural change. The examiner has not attempted to argue that it does not. The examiner has merely pointed out that adding a pigment to a layer does not change the mechanism of the wound dressing, i.e. providing a non-obvious dressing. It is the examiner's position that adding a pigment in view of Lorenz's teachings is obvious since one would add a dye to impart a desired color.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sharmila Gollamudi Landau
Primary Examiner
Art Unit 1616

SGL